

WHAT IS CLAIMED IS:

1 1. A device for percutaneously exposing an outer layer of a body lumen
2 or body cavity of a patient which is covered by an inner layer comprising:
3 a catheter body having a proximal end, a distal end and a lumen therethrough;
4 and
5 a dissection tool disposed near the distal end of the catheter body adapted to
6 expose a portion of the outer layer.

1 2. A device as in claim 1, wherein the body lumen comprises a blood
2 vessel, the inner layer comprises an intimal layer, and the outer layer comprises an adventitial
3 layer.

1 3. A device as in claim 2, wherein the dissection tool comprises a radially
2 expansive element configured to contact the vessel wall in an expanded position.

1 4. A device as in claim 3, wherein the radially expansive element
2 comprises a cutting surface configured to cut through the intimal layer of the vessel wall to
3 expose a portion of the adventitial layer after contact with the vessel wall in the expanded
4 position.

1 5. A device as in claim 4, wherein the cutting surface is configured to cut
2 by rotation of the radially expansive element.

1 6. A device as in claim 3, wherein the radially expansive element
2 comprises an abrasive surface configured to abrade an intimal layer of the vessel wall to
3 expose a portion of the adventitial layer after contact with the vessel wall in the expanded
4 position.

1 7. A device as in claim 6, wherein the abrasive surface is configured to
2 abrade by rotation of the radially expansive element.

1 8. A device as in claim 3, wherein the radially expansive element is
2 advanceable along the exposed portion of the adventitial layer to delaminate the intimal layer
3 from the adventitial layer along a segment of the blood vessel.

1 9. A device as in claim 3, wherein the radially expansive element is self-
2 expandable.

1 10. A device as in claim 3, wherein the radially expansive element is
2 expandable by action of an inflatable member.

1 11. A device as in claim 3, wherein the radially expansive element has an
2 adhesive surface adapted to adhere to an intimal layer of the vessel wall upon contact with the
3 vessel wall in the expanded position.

1 12. A device as in claim 11, wherein the element comprises an inflatable
2 member and the adhesive surface is capable of removing the adhered portions of the intimal
3 layer from the vessel wall to expose portions of the adventitial layer upon deflation of the
4 inflatable member.

1 13. A device as in claim 11, wherein the adhesive surface comprises
2 cyanoacrylate, UV curable adhesive, epoxy, bioadhesives, and collagen based adhesives.

1 14. A device as in claim 11, wherein the adhesive surface comprises a
2 material having a temperature in the range of approximately -100°C to 0°C.

1 15. A device as in claim 11, wherein the adhesive surface comprises a
2 material having a temperature in the range of approximately 42°C to 100°C.

1 16. A device as in claim 2, wherein the dissection tool comprises a radially
2 extensible element configured to contact the vessel wall in an extended position.

1 17. A device as in claim 16, wherein the radially extensible element
2 comprises a pointed instrument configured to cut through an intimal layer of the vessel wall
3 to expose a portion of the adventitial layer after contact with the vessel wall in the extended
4 position.

1 18. A device as in claim 17, wherein the pointed instrument is configured
2 to cut by rotation of the radially extensible element.

1 19. A device as in claim 2, wherein the dissection tool comprises an
2 adhesive element having an adhesive surface configured to contact the vessel wall, the

3 adhesive surface adapted to adhere to an intimal layer of the vessel wall upon contact with the
4 vessel wall.

1 20. A device as in claim 19, wherein the adhesive element is capable of
2 removing the adhered portions of the intimal layer from the vessel wall to expose portions of
3 the adventitial layer upon withdrawal of the adhesive element.

1 21. A device as in claim 19, wherein the adhesive surface comprises a
2 vacuum suction.

1 22. A device as in claim 20, wherein the adhesive surface comprises
2 cyanoacrylate, UV curable adhesive, epoxy, bioadhesives, and collagen based adhesives.

1 23. A device as in claim 19, wherein the adhesive surface comprises a
2 material having a temperature in the range of approximately -100°C to 0°C.

1 24. A device as in claim 19, wherein the adhesive surface comprises a
2 material having a temperature in the range of approximately 42°C to 100°C.

1 25. A device as in claim 2, further comprising a stripping tool adapted to
2 be received within the catheter body lumen, said stripping tool comprising a stripping
3 component configured to contact the exposed portion of the adventitial layer and advance
4 along the exposed portion to delaminate the intimal layer from the adventitial layer along a
5 segment of the blood vessel.

1 26. A device as in claim 25, wherein the stripping tool further comprises a
2 shaft having a proximal end, a distal end and a threaded surface along at least a portion of its
3 length, wherein the stripping component is mounted on the shaft so that rotation of the shaft
4 advances the stripping component along the shaft.

1 27. A device as in claim 26, wherein the stripping component is mounted
2 on the shaft so that rotation of the shaft linearly advances the stripping component along the
3 shaft without rotating the stripping component.

1 28. A device as in claim 25, wherein the stripping component comprises a
2 radially expansible ring positionable between the intimal and adventitial layers so that the
3 intimal layer passes through the inside of the ring during advancement.

29. A device as in claim 28, wherein the catheter further comprises an aspiration lumen and the stripping component further comprises a funnel shaped dissection propagator connected to the ring to guide the delaminated intimal layer into the aspiration lumen.

30. A device as in claim 29, wherein the catheter further comprises a macerating element within the aspiration lumen and/or dissection propagator to macerate the delaminated intimal layer.

31. A device as in claim 25, wherein the stripping component comprises at least one radially expandable arm having a blunt-end tip configured to be positionable between the intimal and adventitial layers so that the intimal layer is delaminated as the stripping component is retracted.

32. A device as in claim 25, wherein the stripping component comprises a radially expansible coil positionable between the intimal and adventitial layers so that the intimal layer passes through the inside of the coil during advancement.

33. A device as in claim 32, wherein the coil has an oblique angle formed leading edge and the coil is advanceable by rotation.

34. A device as in claim 25, further comprising a mechanical pump adapted to be received within the catheter body lumen.

35. A device as in claim 34, further comprising a macerating element located at least partially along the length of said mechanical pump.

36. A device as in claim 25, wherein the stripping component comprises a rod having an atraumatic distal tip, the rod being angularly extendable from the catheter body and the tip being configured to be positionable between the intimal and adventitial layers.

37. A device as in claim 36, wherein the rod is rotatable around a longitudinal axis of the catheter body.

38. A device as in claim 36, wherein the rod is angularly and/or extendably adjustable.



1 46. A device as in claim 2, further comprising a cutting tool adapted to be
2 received within the catheter body lumen, said cutting tool comprising a ring configured to be
3 advanceable along a cleavage plane between a delaminated intimal layer and the adventitial
4 layer.

1 47. A device as in claim 46, wherein the ring comprises a support tube and
2 a cutting wire, wherein the support tube is retractable to expose the cutting wire which is
3 configured to cut through the delaminated intimal layer when tensioned.

1 48. A device for percutaneously exposing an outer layer of a body lumen
2 or body cavity of a patient which is covered by an inner layer comprising:
3 a catheter body having a proximal end, a distal end, and a lumen therethrough;
4 and
5 a dissection means disposed near the distal end of the catheter body for
6 exposing a portion of the outer layer.

1 49. A device as in claim 48, further comprising a stripping means adapted
2 to be received within the catheter body lumen for delaminating the inner layer from the outer
3 layer.

1 50. A device as in claim 49, further comprising a cutting means adapted to
2 be received within the catheter body for cutting through and releasing the delaminated inner
3 layer.

1 51. A device for percutaneously delaminating an inner layer of a body
2 lumen of a patient from an outer layer comprising:
3 a catheter body having a proximal end, a distal end, and a lumen therethrough;
4 and
5 means mounted on the catheter body for elongating a segment of the body
6 lumen to cause delamination of the inner layer from the outer layer.

1 52. A device as in claim 51, wherein the means for elongating comprises a
2 proximal occlusion member and a distal occlusion member which are capable of moving
3 apart thereby elongating the segment.

1 53. A device as in claim 51, further comprising macerating means for
2 macerating the delaminated inner layer.

1 54. A system for percutaneously treating a body lumen or body cavity of a
2 patient comprising:

3 a dissection catheter having a proximal end, a distal end, and a dissection
4 means disposed near its distal end for dissecting the inner layer to expose a portion of the
5 outer layer; and

6 a stripping catheter having a proximal end, a distal end, and a stripping means
7 disposed near its distal end to advance along the exposed portion of the outer layer for
8 delaminating the inner layer from the outer layer.

1 55. A system as in claim 54, further comprising a cutting catheter having a
2 proximal end, a distal end, and a cutting means disposed near its distal end for cutting
3 through the delaminated inner layer for removal.

1 56. A system for percutaneously treating an occlusion in a blood vessel of
2 a patient comprising:

3 a dissection catheter having a proximal end, a distal end and a dissection tool
4 disposed near the distal end adapted to expose a portion of the adventitial layer; and

5 a stripping catheter having a proximal end, a distal end and a stripping tool
6 disposed near the distal end adapted to contact the exposed portion of the adventitial layer
7 and advance along the exposed portion to delaminate the intimal layer from the adventitial
8 layer along a segment of the blood vessel.

1 57. A system as in claim 56, wherein the dissection tool comprises a
2 radially expansive element configured to expose a portion of the adventitial layer upon
3 contact with the vessel wall in an expanded position.

1 58. A system as in claim 56, wherein the dissection tool comprises a
2 radially extensible element configured to expose a portion of the adventitial layer upon
3 contact with the vessel wall in an expanded position.

1 59. A system as in claim 56, wherein the dissection tool or the stripping
2 tool comprises an adhesive element having an adhesive surface configured to contact the

3 vessel wall, the adhesive surface adapted to adhere to an intimal layer of the vessel wall upon
4 contact with the vessel wall.

1 60. A system as in claim 59, wherein the adhesive element removes the
2 adhered portions of the intimal layer from the vessel wall to expose portions of the adventitial
3 layer upon withdrawal of the adhesive element.

1 61. A system as in claim 59, wherein the adhesive surface comprises a
2 vacuum suction.

1 62. A system as in claim 56, wherein the stripping tool comprises a
2 stripping component comprising a radially expansible ring positionable between the intimal
3 and adventitial layers so that the intimal layer passes through the inside of the ring during
4 advancement.

1 63. A system as in claim 56, wherein the stripping catheter further
2 comprises body lumen and a mechanical pump adapted to be received within the body lumen.

1 64. A system as in claim 63, further comprising a macerating element
2 located at least partially along the length of the mechanical pump.

1 65. A method of percutaneously removing an occlusion from a site within
2 blood vessel of a patient comprising the following steps:
3 providing a catheter having a proximal end, a distal end, a lumen therethrough,
4 and a dissection tool disposed near the distal end;
5 introducing the catheter into the vessel and advancing the dissection tool to the
6 site of the occlusion to be treated; and
7 contacting the vessel wall near the site with the dissection tool to expose a
8 portion of an adventitial layer.

1 66. A method as in claim 65, wherein the dissection tool comprises a
2 radially expansive element and the contacting step further comprises radially expanding the
3 element so that the element contacts the vessel wall.

1 67. A method as in claim 66, wherein the radially expansive element has a
2 cutting surface and the radial expansion disposes the cutting surface against the vessel wall to
3 cut through the intimal layer and expose the portion of the adventitial layer.

1 68. A method as in claim 66, wherein the radially expansive element has
2 an abrasive surface and the contacting step further comprises manipulating the element so
3 that the abrasive surface abrades through the intimal layer to expose the portion of the
4 adventitial layer.

1 69. A method as in claim 67 or 68, further comprising rotating the radially
2 expansive element to assist in exposing the portion of adventitial layer.

1 70. A method as in claim 67 or 68, further comprising advancing the
2 radially expansive element along the exposed portion of the adventitial layer to delaminate
3 the intimal layer from the adventitial layer along a segment of the blood vessel.

1 71. A method as in claim 66, wherein the radially expansive element
2 comprises an inflatable member having an adhesive surface and the contacting step includes
3 inflating the inflatable member to adhere the adhesive surface to an intimal layer of the vessel
4 wall and subsequently deflating the member to remove the adhered portions of the intimal
5 layer from the vessel wall to expose portions of the adventitial layer.

1 72. A method as in claim 63, wherein the dissection tool comprises a
2 radially extensible element and the contacting step further comprises radially extending the
3 element so that the element contacts the vessel wall.

1 73. A method as in claim 72, wherein the radially extensible element has a
2 pointed instrument and the contacting step further comprises rotating the element to assist in
3 exposing the portion of adventitial layer.

1 74. A method as in claim 65, wherein the dissection tool comprises an
2 adhesive element and the contacting step includes adhering the adhesive element to an
3 intimal layer of the vessel wall and subsequently withdrawing the element to remove the
4 adhered portions of the intimal layer from the vessel wall to expose portions of the adventitial
5 layer.

1 75. A method as in claim 65, further comprising introducing a stripping
2 tool having a stripping component and advancing the stripping component along the exposed
3 portion of the adventitial layer to delaminate the intimal layer from the adventitial layer along
4 a segment of the blood vessel.

76. A method as in claim 75, wherein the stripping tool comprises a shaft having a proximal end, a distal end, and a threaded surface along at least a portion of its length wherein the stripping component is mounted on the shaft in a locked position, and the method further comprises rotating the shaft which advances the stripping component along the segment of the blood vessel.

77. A method as in claim 75, wherein the stripping component comprises a radially expansible ring, and the method further comprises positioning the ring between the intimal and adventitial layers so that the intimal layer passes through the inside of the ring during advancement.

78. A method as in claim 77, wherein the ring comprises a support tube and a cutting wire and the method further comprises:

- retracting the support tube to expose the cutting wire; and
- tensioning the cutting wire to cut through the intimal tissue and release the delaminated intimal tissue from the vessel wall.

79. A method as in claim 78, further comprising macerating the delaminated intimal tissue and removing the tissue through an aspiration lumen in the catheter.

80. A method as in claim 75, wherein the stripping component comprises a radially expansible coil, and the method further comprises positioning the coil between the intimal and adventitial layers so that the intimal layer passes through the inside of the coil during advancement.

81. A method as in claim 80, further comprising advancing the coil by rotation.

82. A method as in claim 75, further comprising macerating the delaminated intimal tissue and removing the tissue through an aspiration lumen in the catheter.

83. A method as in claim 75, wherein the stripping component comprises a rod having an atraumatic tip, and the method further comprises angularly extending the rod from the catheter body and positioning the tip between the intimal and adventitial layers.

1 84. A method as in claim 75, wherein the stripping component comprises
2 an inflatable member having an angioscope disposed within, and the method further
3 comprises inflating the member within the blood vessel and visualizing with the angioscope
4 the advancing step of the member along the exposed portion of the adventitial layer.

1 85. A method as in claim 84, wherein the stripping tool further comprises
2 an anchoring component, and the method further comprises anchoring the component within
3 the blood vessel so that it remains in place during advancement of the stripping component.

1 86. A method as in claim 75, further comprising:
2 occluding the blood vessel proximal to the stripping component with a
3 proximal occlusion member;
4 occluding the blood vessel distal to the stripping component with a distal
5 occlusion member;
6 providing a visualization means within the blood vessel between the occlusion
7 members so that the advancement step is visualized by the visualization means.

1 87. A method as in claim 86, further comprising filling the vessel between
2 the occlusion members with saline.

1 88. A kit for percutaneously treating an occlusion in the vessel of a patient
2 comprising:
3 a percutaneous catheter having a proximal end, a distal end, a lumen
4 therethrough and a dissection tool disposed near the distal end adapted to expose a portion of
5 the adventitial layer; and
6 instructions for use including the following methods:
7 introducing the catheter into the vessel and advancing the dissection tool to the
8 site of the occlusion to be treated; and
9 contacting the vessel wall with the dissection tool to expose a portion of an
10 adventitial layer.

1 89. A kit as in claim 88, further comprising a percutaneous stripping tool
2 and said instructions for use further including advancing the stripping tool along the exposed
3 portion of the adventitial layer to delaminate an intimal layer from the adventitial layer along
4 a segment of the blood vessel.

90. A kit as in claim 88, further comprising an aspiration catheter.

91. A kit as in claim 88, further comprising an adhesive material for application to an adhesive surface.

92. A system for percutaneously treating a body lumen or body cavity of a patient having an inner layer covered by an outer layer comprising:

a dissection catheter having a proximal end, a distal end and a dissection tool disposed near the distal end adapted to expose a portion of the inner layer; and

a stripping catheter having a proximal end, a distal end and a stripping tool disposed near the distal end adapted to contact the exposed portion of the inner layer and advance along the exposed portion to delaminate the outer layer from the inner layer along a segment of the body lumen.

93. A method of percutaneously treating a target location within a body lumen of a patient having an inner layer covered by an outer layer comprising the following steps:

providing a catheter having a proximal end, a distal end, a lumen therethrough, and a dissection tool disposed near the distal end;

introducing the catheter into the body lumen and advancing the dissection tool near the target location; and

contacting the outer layer near the target location with the dissection tool to expose a portion of the underlying inner layer.

94. A kit for percutaneously treating a target location within a body lumen or body cavity of a patient having an inner layer covered by an outer layer comprising:

a percutaneous catheter having a proximal end, a distal end, a lumen therethrough and a dissection tool disposed near the distal end adapted to expose a portion of the inner layer; and

instructions for use including the following methods:

introducing the catheter into the vessel and advancing the dissection tool to the target location; and

contacting the outer layer with the dissection tool to expose a portion of the inner layer.